Market Release
November 22 2018

FINANCIAL RESULTS FOR HALF YEAR ENDED 30 SEPTEMBER 2018

AFT Pharmaceuticals Limited (NZX; AFT, ASX; AFP) today announced its half-year unaudited financial results for the period ended 30 September 2018 (**H1FY19**).

Performance Highlights

- **Operating Revenues** of $38.0m for the first half of FY2019 to 30 September 2018 (H1FY2019) were up 4% over the previous corresponding six month period (PCP) ended 30 September 2017 (H1FY18).
- **Operating Revenues** from the over-the-counter channel were up 20% over the PCP.
- **Gross Profit** grew by 24% to $17.8m.
- **Operating Loss** of $0.1m (PCP $6.7m) has improved significantly with the strong growth in Gross profit and the reduction in the Research and Development expense as the clinical trial programmes are completed.
- ***Maxigesic*** is now being sold in fifteen countries – Australia, Brunei, El Salvador, Israel, Iraq/Kurdistan, Ireland, Italy, Malaysia, Malta, New Zealand, Nicaragua, Serbia, Singapore, United Kingdom and United Arab Emirates. Further country launches are in progress.
- ***Maxigesic*** is licensed in 128 countries up from 125 in FY2018.
- **Product clinical studies** on track with most of the programme from the IPO now completed. There will be five clinical trials in progress during FY2019.
- ***Nasosurf*** device development has also advanced with some device redesign required following the initial human factor studies in USA and filing for Class IIA Medical Device registration in the USA is targeted for April/May 2019.
- **Research and Development** expensed investment in our key global products has reduced to $2.6m[1] for the six months (PCP $5.6m) and represents 7% of Operating Revenue (PCP 15%). We have now completed most of the clinical trial programmes that we identified at the time of IPO. Additional dose forms such as *Maxigesic Rapid* have been developed within the existing clinical trial budget and a new *Maxigesic* cold & flu formulation is under development but these costs are not material.
- **Cash available** at 30 September 2018 of $7.4m (PCP $7.1m).

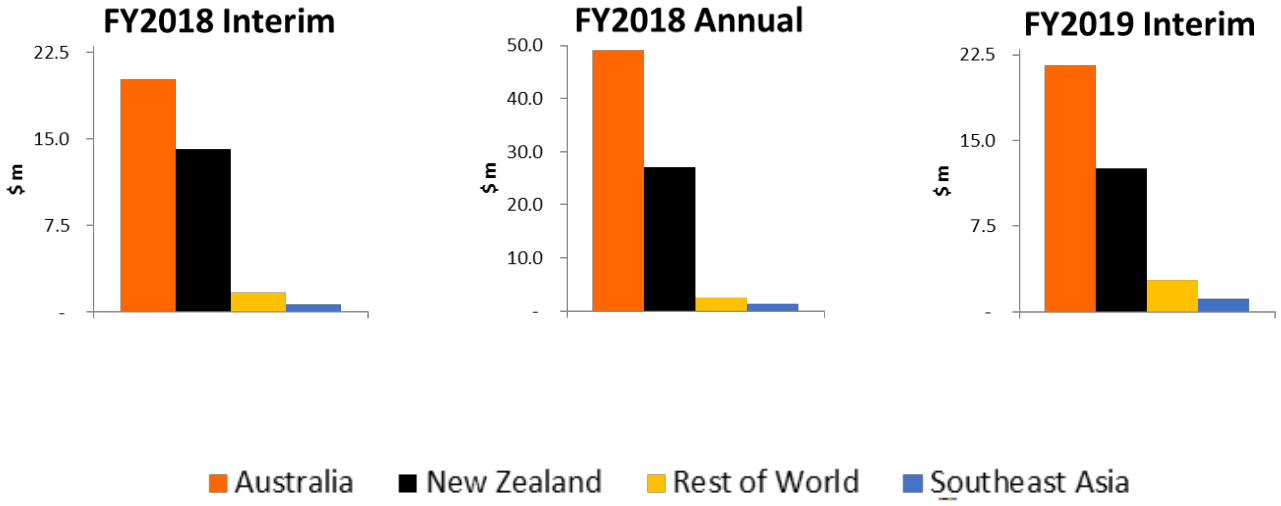
Financial Overview

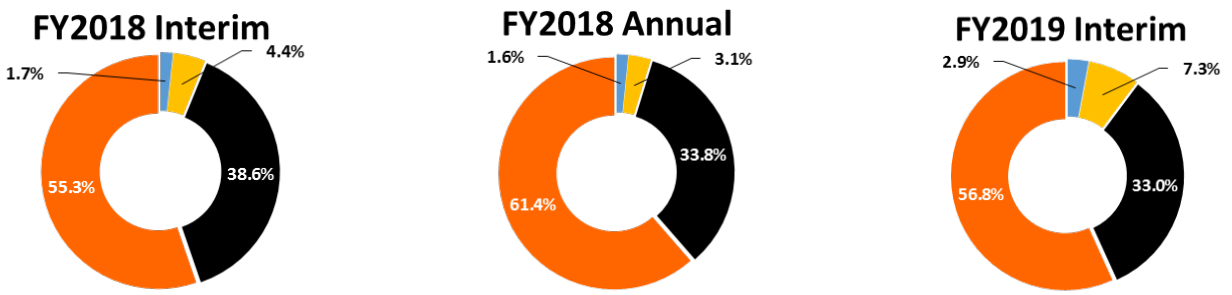
Group Operating Results NZ$'000	Six Month Period Ended September 30		Change ($)	Change (%)
	FY2019	FY2018		
Revenue	**38,045**	**36,561**	**+ 1,484**	**+ 4**
Cost of Sales	(20,292)	(22,256)	- 1,964	- 9
Gross Profit	**17,753**	**14,305**	**+ 3,448**	**+ 24**
Other Income	2,430	1,014	+ 1,416	+ 140
Selling and distribution expenses	(14,234)	(12,771)	+ 1,463	+ 11
General and administrative expenses	(3,489)	(3,618)	- 129	- 4
Research and development expenses	(2,225)	(4,982)	- 2,757	- 55
Equity Accounted Loss of joint venture entity	(344)	(616)	- 272	- 44
Underlying Operating Loss	**(109)**	**(6,668)**	**- 6,559**	**- 98**

Operating Revenue

Operating Revenue grew 4% to $38.0m for the six month period ended 30 September 2018 (PCP $36.6m) with the continued growth in our primary Australian market and the emerging Rest of World and Southeast Asia markets offset by the trading out of lower margin products, most noticeably in New Zealand. Operating revenue in the over-the-counter channel grew by 20% (PCP 20%). The upside of these revenue shifts has been the 24% growth in gross profit. The implementation of the new reporting standard NZ IFRS15 has not changed the timing or amount of revenue recognised in operating revenue.

The following tables set out revenues from our four markets:





- **Australia Revenue** grew by 7% to $21.6m (PCP $20.2m) and this market now makes up 57% of Group Operating Revenue. Strong growth, up 17%, continued in its main over-the-counter channel. *Maxigesic* grew two fold over the PCP following the shift of codeine based painkillers from over-the-counter to prescription only in February 2018 and maintains its leadership of the combination product section of the market. The launch of *Novatears* at the beginning of the year further supplements the eye care range which continued to experience good growth. The Hospital channel retracted by 10% with the trading out of lower margin products. The new Hospital products being introduced, which are at higher margins, will replace this revenue by the end of FY2019 or early in FY2020. The prescription channel grew by 10% on existing products.

- **New Zealand Revenue** declined by 11% to $12.6m (PCP $14.1m) and now represents 33% of the Group Operating Revenue. The decline is due to the trading out of lower margin products at the end of FY2018 in the Hospital channel, the ceasing of the sole supply tender prescription product *Metoprolol* with the final sales made in FY2018 and some price reductions on other tender products. The upside of this shift from lower margin product is that Gross Profit in New Zealand grew by 23%. The over-the-counter channel experienced good revenue growth, up 9%. *Maxigesic* also grew two fold in New Zealand, and also as with Australia, the launch of *Novatears* at the beginning of the year further supplemented the

eye care range which continued to experience good growth. *Vitamin C Liposachets* were launched at the beginning of the year and are selling well.

- **Rest of World Revenue** grew by 70% to $2.8m (PCP $1.6m) and now represents 7% of Group Operating Revenue. Most of the revenue is from *Maxigesic* sales and royalties with sales in this half made to Italy, Ireland, Israel, Iraq, United Arab Emirates and the Central American Common Market (CACM). Further launches are imminent and are dictated by regulatory timelines.
- **Southeast Asia Revenue** grew by 81% to $1.1m (PCP $0.6m) and represents 3% of the Group Operating Revenue. Most of this growth is from the launch of *Maxigesic* in Malaysia with the initial sell in to the distributor there and the re-launch of *Maxigesic* in Singapore with its re-classification to an over-the-counter product.

Gross Margin

Gross Profit grew 24% to $17.8m (PCP $14.3m) driven by the operating revenue growth of 20% in the higher margin over-the-counter channel and the trading out of lower margin tender products in the Hospital and Prescription channels. The Gross Profit Margin accordingly improved to 47% (PCP 39%), driven by this growth of the higher margin over-the-counter products in all markets.

We expect the Gross Profit Margin to remain in this zone as the over-the-counter products particularly in Australia and Rest of World markets continue to grow.

Other Income

Licensing Income comprises the upfront and milestone fees from out licensing arrangements we have in our Rest of World markets and the fees we have received from the divestment of non-core hospital products. It is classified in the Financial Statements as Other Income. These totalled $2.2m (PCP $0.8m), with a combination of new out licensing agreements commencing and milestones on existing agreements, together with the divestment fees. The implementation of the new reporting standard NZ IFRS15 has not materially changed the timing or amount of licence income recognised in operating revenue.

The balance of Other Income of $0.2m (PCP $0.2m) is the *Callaghan Innovation* growth grant that we receive on eligible research and development expenditure.

Operating Overheads

- **Research and Development** investment reduced to $2.2m (PCP $5.0m), and in addition our 50% of the spend on *Pascomer* reduced to $0.3m (PCP $0.6m). This is reported under joint venture equity accounting in the Financial Statements as required by GAAP.

  We have now completed most of the clinical trial programmes that we identified at the time of IPO. This has resulted in a number of publications in scientific journals during this year. *Maxigesic 325* results have been published in the major US journal *Clinical Therapeutics, Maxigesic* Oral Liquid study results have resulted in 2 publications and the pivotal *Maxigesic* IV study has been submitted to a major US journal. A further two publications are in preparation covering pharmacokinetics of the different *Maxigesic* dose forms and a further study on consolidated safety data. This data is important to back up commercialization and key marketing claims.

Completion of this development work has also allowed commencement of regulatory filings of both *Maxigesic* IV and Oral Liquid. Additional oral dose forms, hot drink sachets and dry stick sachets are still in development and regulatory filings are targeted to commence within the 2019 calendar year.

A pre-NDA filing meeting with FDA for *Maxigesic* IV has clarified some additional data requirements and this will result in some additional clinical trial expenditure before the USA regulatory filing which again is targeted within 2019 calendar year.

Formulation work has been completed on a fast dissolving formulation, *Maxigesic Rapid* which utilizes proprietary technology in-licensed from a US company. Additionally a new product, *Maxigesic Cold & Flu* is being developed for treatment of cold & flu which will be commercially attractive for the Australian market and additional territories. The development costs for this programme are modest and not expected to contribute significantly to R&D costs.

The key aim is now to complete US registrations and to commercialize *Maxigesic* and its line extensions in major markets.

The *Pascomer* development programme has confirmed that the formulation is stable at room temperature which was challenging as the active ingredient is easily oxidized in topical formulations. A significant preclinical development programme has now been completed culminating with a successful FDA meeting to open the IND and obtain clearance to initiate clinical studies in patients. Options to fund this significant clinical development programme are currently being investigated.

NasoSURF device development has also advanced with some device redesign required following the initial human factor studies in USA. Human factors are a relatively new regulatory requirement and a further additional human factor study will be required after completion of the redesigned engineering batches.

Initial clinical distribution studies are underway in Sydney and a further study in New Zealand is to commence prior to the end of calendar Q1 2019. Class II Medical Device filing in USA is targeted for April/May 2019 which is a quarter behind schedule necessitated by the redesign features identified in the human factor studies. The key remains the initiation and completion of the clinical programme which is targeted to start during FY2020 after approval to open an IND is obtained from US FDA.

- **Selling and Distribution** expenses increased by 11% to $14.2m (PCP $12.8m) in support of the 20% revenue growth in the over-the-counter channel, particularly in Australia. We continually monitor this spend and some efficiencies have been identified which are being implemented during the H2FY19 time period in Australia and the Asian markets.
- **General and Administration** expenses reduced to $3.5m (PCP $3.6m) with cost savings made where possible.

Cash Flow and Balance Sheet

Total Assets of $59.4m are up on the March 2018 year end's $56.6m. This is mainly due to the capitalised investment made into research and development both directly and through the joint venture.

Working Capital increased to $26.3m (PCP $24.1m) with the $4.1m increase in inventory to $27.8m (PCP $23.7m) for the stock build for the larger sales volumes during the summer months together with

the $0.2m increase in trade payables and provisions to $14.5m (PCP $14.7m), offset by the $2.0m reduction in receivables and prepayments to $13.0m (PCP $15.0m).

Cash holdings of $7.4m are up from the $6.8m at the March 2018 year end, primarily reflecting the breakeven underlying operating result and the drawdown under the term loan facility.

The long term CRG loan of $42.0m has a maturity date of 31 March 2020. The company are working with CRG to extend the existing facility and expand the available capital to US$40-50m.

Product Development

- ***Maxigesic*** is now being sold in fifteen countries – Australia, Brunei, El Salvador, Israel, Iraq/Kurdistan, Ireland, Italy, Malaysia, Malta, New Zealand, Nicaragua, Serbia, Singapore, United Kingdom and United Arab Emirates. The company founder personally attended launch meetings to give talks on Maxigesic to Healthcare Professionals in Malaysia and Ireland. Further country launches are in progress with exact timings dependent upon multiple factors around the finalising of the regulatory processes at a country and licensee level. These are either completing registration updates or the transfer of existing registrations to local licensees in Europe. Getting to launch requires a number of steps in each country and these timings are hard to forecast. Launch planning is currently underway in a number of significant countries or regions such as Belgium, Eastern Europe, France, Mexico, Portugal and Spain.

  Registration in the remaining EU countries (Cyprus, Greece and Lithuania) is currently being finalised and additional filings in a number of countries in Africa and the Middle East, which are reliant upon an EU registration, are underway. The recent registration in Mexico has been re-scheduled to over-the-counter status. The Netherlands, Portugal and Spain have also achieved over-the-counter status.

  Maxigesic is now licensed in 128 countries with the recent addition of Russia, South Korea, Taiwan and Hong Kong. A few additional territories remain on our targeted list: USA, Canada, Germany and selected territories in South America with discussions underway in most of these currently.

  Maxigesic IV out-licensing discussions are now underway which once achieved will contribute significantly to other income as up fronts are anticipated in general to be larger than for the oral formulations. The first out-licensing deal has recently been signed for South Korea.

  Maxigesic sales in the Rest of World are starting to grow and contributions will become more significant once additional countries and dose forms are added. In following years the contribution will become significant and for the first time we have seen during H1 FY19, the sales from the Rest of the World and Southeast Asia exceeding 10% of the group operating revenue. Important features of Rest of World sales are that overhead costs are lower so more of the profit contribution is realised in the profit line.

- **Product clinical studies**. The majority of the R&D programme flagged in the IPO has now been completed for *Maxigesic* oral dose forms which has been a significant exercise. Additional dose forms such as *Maxigesic Rapid* have been developed within the existing clinical trial budget and a new *Maxigesic* cold & flu formulation is under development but these costs are not material.
  Additional specific *Maxigesic IV* data for the USA filing is required and this is being organized to commence during the 2019 calendar year.

Pascomer patient clinical studies are being planned and alternatives to fund this significant programme are being currently investigated.

- ***NasoSURF*** development is proceeding with the US Food and Drug Administration development pathway confirmed. Class I Medical Device has been completed. However, the major market opportunities lie in indications covered by a Class II Medical Device registration pathway which is consequently the targeted opportunity and underway. Human Factor study results required some redesign work which is well underway.

  Following preclinical programme completion and final Human Factor Studies, an IND with FDA will be opened and clinical studies commence. This will be in FY2020. Consequently, some of the spend will be delayed which will offset, to some extent, the additional spend required for *Maxigesic IV.*

The company will continue to carefully run its Research and Development budgets to stay within profit targets.

Outlook

Sales continued to grow in Australia but were soft in the first quarter due to divestment of Claris Hospital Products and the effects of the planned Australian Pharmacy stocking up with *Maxigesic* prior to the 1 February 2018 re-scheduling of codeine-based painkillers from over-the-counter to prescription. However, growth is picking up again and additional hospital products with better margins are being launched and will continue to be launched over the next few years.

Additionally, market research identified that there was a considerable amount of stock piling of codeine-based products with a significant number of consumers buying up to 12 months' worth of product. Hence there remains an ongoing opportunity to encourage consumers to switch from codeine medications. *Maxigesic* has obtained a market leadership position in Australia for paracetamol-ibuprofen combinations. We see the opportunity for significant ongoing organic growth from *Maxigesic* tablets and additional dose forms such as *Maxigesic IV* and *Maxigesic Oral Liquid* which are planned to be launched in the next 12-18 months. Further sales growth from our eye care channel is also expected together with a number of new product launches.

Top line sales declined in New Zealand due to the divestment of Claris Hospital Products and the final effects of the Metoprolol tender sales being lost. However, we have continued to transition sales to products in the over-the-counter market resulting in the positive growth of gross margins and overall gross profit. We expect this gross profit sales growth to continue in New Zealand which has been helped by organic sales growth in over-the-counter products and new product launches *Maxigesic PE, NovaTears* and *Vitamin C Liposachets.*

The timing of Rest of World sales still remains difficult to determine due to the multitude of countries and differing regulatory requirements and related timelines. Further launches have occurred and are ongoing with a number of significant markets being close to launch. The estimates from licensees continue to indicate that the sales will increase significantly over the next few years with new launches, growth in already launched markets, and new line extensions.

Further progress has been achieved in the out-licensing programme with the addition of a significant major market, Russia, for *Maxigesic* oral dose forms and our first significant *Maxigesic IV* deal with a licensee in South Korea. Additional discussions are currently underway for the remaining oral dose form and IV territories which once achieved will add significantly to Other Income. As commercial sales milestones are achieved under our existing out licensing programme they will provide further licence income.

The clinical trial programmes have progressed well with a significant proportion successfully completed thereby considerably reducing the clinical risk for the *Maxigesic* programme. Further R&D costs are required for the *Maxigesic IV* USA programme in addition to the two new lines, *Maxigesic Rapid* and *Maxigesic Cold & Flu*.

Market research has identified that the *NasoSURF* project represents a significant commercial opportunity. Completion of this programme in order to file the registration in major territories will become a major development focus in FY2020.

Completing additional trials within existing financial resources remains the key aim and as signalled we remain confident that we will return to profitability during the FY2019 time period. The small operating loss during 1H FY2019 is positive progress and we expect the second half of the financial year to generate greater revenues and profitability than the first half.

[End of release]

For more information:

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About AFT

AFT is a growing multinational pharmaceutical business with a broad range of products, both developed itself and in-licensed from third parties. AFT's products cover all major pharmaceutical distribution channels: over-the-counter, prescription and hospital. Historically, AFT's home markets have been Australia, New Zealand and South-East Asia. However the company is out-licensing its own products to licensees and distributors to sell in an increasing number of countries around the world. The company's intensive Research and Development programme forms the basis of its international sales strategy. For more information about the company, visit our website www.aftpharm.com.